

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

MARLA JENSEN AND AMANDA MONTEFINESE *ex rel.* UNITED STATES OF AMERICA, and THE STATES OF CALIFORNIA, FLORIDA, ILLINOIS, NEW JERSEY, NEW YORK, RHODE ISLAND, TEXAS, MARYLAND, CONNECTICUT, and THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA,

Plaintiffs,

v.

GENESIS LABORATORY, *et al.*,

Defendants.

Civil Action No. 20-15121 (GC) (TJB)

OPINION

CASTNER, District Judge

THIS MATTER comes before the Court upon Defendants Genesis Laboratory Management, LLC's (Genesis) and Metropolitan Healthcare Billing, LLC's (Metropolitan) Motion to Dismiss Plaintiffs'/Relators'¹ Second Amended Complaint (SAC) (ECF No. 32) pursuant to Federal Rule of Civil Procedure (Rule) 12(b)(6). (ECF No. 44.) Relators opposed (ECF Nos. 46-47²), and Defendants replied (ECF No. 48). The Court held oral argument on

¹ Marla Jensen and Amanda Montefinese, as Relators, bring this civil action on behalf of the United States of America, the States of California, Florida, Illinois, New Jersey, New York, Rhode Island, Texas, Maryland, Connecticut, and the Commonwealths of Massachusetts and Virginia. (ECF No. 32.) *See United States v. Janssen Biotech, Inc.*, 576 F. Supp. 3d 212, 223 (D.N.J. 2021) (“A private plaintiff (or relator) may bring a civil action on behalf of the United States to enforce the [False Claims Act] and may receive a share of any recovery resulting from the lawsuit.”)

² Plaintiffs filed the same response twice on the Court’s docket. (*See* ECF No. 46-47.) The first response was filed under seal. (ECF No. 46.)

February 13, 2025. (ECF No. 53.) After careful consideration of the parties' submissions and arguments, and for the reasons set forth below, and other good cause shown, Defendants' Motion to Dismiss is **GRANTED**.

I. **BACKGROUND**³

Relators filed this *qui tam* action against Defendants for allegedly (1) submitting false claims to federal and state health care programs for “medically unnecessary” services and (2) waiving copayments and other cost sharing required by those programs in violation of the Anti-Kickback statute, 42 U.S.C. § 1320a-7b(b). (*See generally* ECF No. 32.)

A. Relevant Statutes

The Court begins by reviewing the relevant statutes in this case to provide context for Relators' allegations in the SAC.

1. Medicare

The present dispute arises in the context of the Medicare and Medicaid payment systems. (*See generally id.*) “Medicare is a federal health insurance program for individuals with disabilities and the elderly,” *United States ex rel. Simpson v. Bayer Corp.*, 376 F. Supp. 3d 392, 397 (D.N.J. 2019), and is administered by the Centers for Medicare and Medicaid Services (CMS), *Landau v. Lucasti*, 680 F. Supp. 2d 659, 661 (D.N.J. 2010). “Medicare Part A covers inpatient hospital services and items used during inpatient stays.” *Simpson*, 376 F. Supp. 3d at 397 (citing 42 U.S.C. § 1395c). Medicare Part B “is a voluntary, federally subsidized health insurance program that covers medical expenses . . . not covered under Part A of the program.” *Am. Ambulance Serv. of*

³ On a motion to dismiss under Rule 12(b)(6), the Court must accept all facts as true, but courts “are not bound to accept as true a legal conclusion couched as a factual allegation.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citation and quotations omitted).

Pa., Inc. v. Sullivan, 911 F.2d 901, 903 (3d Cir. 1994) (citing 42 U.S.C. § 1395j). Part B includes medical expenses for laboratory diagnostic testing. *See* 42 C.F.R. § 410.32 (2016)).

a. Reimbursements for Laboratory Testing under Medicare

Under Medicare Part B, entities, like Defendants, can submit claims for reimbursement of services provided by physicians. *Id.* § 410.32(d). The Medicare regulations require “the physician . . . who orders the service [to] maintain documentation of medical necessity in the beneficiary’s medical record.” *Id.* § 410.32(d)(2)(i). Additionally, “the entity submitting the claim must maintain . . . [t]he documentation that it receives from the ordering physician or nonphysician practitioner,” and must ensure that the documentation that the entity “submitted with the claim accurately reflects the information it received from the ordering physician or nonphysician practitioner.” *Id.* at § 410.32(d)(2)(ii). Importantly, “no payment may be made under [Medicare] part A or part B for any expenses incurred for items or services . . . which[] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 410.32(d)(3)(ii). Laboratory tests “that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are not covered except when there is a statutory provision that explicitly covers tests for screening.” *See* Medicare Claims Processing Manual: Chapter 16 - Laboratory Services (“Processing Manual”) § 120.1 (issued Jan. 4, 2024).⁴

Entities seeking reimbursement for services provided to Medicare patients are required to submit a CMS-1500 form, which details the precise services provided. *United States v. Andover*

⁴ “The Court may take judicial notice of a ‘public record[.]’” *Calabria Ristorante, Inc. v. Ruggiero Seafood, Inc.*, 706 F. Supp. 3d 489, 502 n.7 (D.N.J. 2023) (quoting *Doe v. Princeton Univ.*, 30 F.4th 335, 342 (3d Cir. 2022)). Additionally, the SAC cites to the Processing Manuel. (*See, e.g.*, ECF No. 32 ¶¶ 24, 27.)

Subacute & Rehab Servs. One, Inc., Civ No. 12-03319, 2019 WL 4686963, at *2 n.8 (D.N.J. Sept. 26, 2019); *United States ex rel. Groat v. Boston Heart Diagnostics Corp.*, 255 F. Supp. 3d 13, 18 (D.D.C. 2017) (*Groat I*) (citing *United States ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707, 711 (6th Cir. 2013)). (See ECF No. 32 ¶¶ 35-36.) When a laboratory submits a CMS-1500 form, a laboratory “is permitted to rely on the ordering physician’s determination that the laboratory tests billed to Medicare are medically necessary.” *United States ex rel. Groat v. Boston Heart Diagnostics Corp.*, 296 F. Supp. 3d 155, 160 (D.D.C. 2017) (*Groat II*) (reconsideration of *Groat I*); *Hobbs*, 711 F.3d at 711 (“The CMS-1500 form requires the provider to ‘certify that the services listed . . . were medically indicated and necessary to the health of [the] patient and were personally furnished by [the physician] or [the physician’s] employee under [the physician’s] personal direction.’”).

b. Fee Schedule for Laboratory Testing under Medicare

Of relevance to the present matter is the Protecting Access to Medicare Act of 2014 (PAMA), Pub. L. No. 113-93 § 216, which added provisions to the Social Security Act, 42 U.S.C. § 1305 *et seq.*, related to the payment and coverage of clinical laboratory testing. Processing Manual § 20. PAMA allows CMS to establish coverage methodologies for clinical laboratory tests defined in the annually updated clinical fee schedule. *Id.* The fee schedule outlines the amount CMS will pay laboratories for certain tests performed. *Id.* Importantly, “[c]o-payments and deductibles do not apply to services paid under the Medicare clinical laboratory fee schedule.” *Id.* at § 20.3; see *United States ex rel. PCTLs, LLC v. Northwestern Mem’l Healthcare*, 2023 WL

6388328, at *5 (N.D. Ill. Sept. 29, 2023) (quoting CMS, Clinical Laboratory Fee Schedule (Jan. 2, 2020), perma.cc/Q282-YW5L). (*See also* ECF No. 32 ¶ 48; ECF No. 47 at 19-20.⁵)

2. Medicaid

Medicaid is “a health insurance program for low-income people that is jointly funded by the federal and state governments.” *United States v. Kindred Healthcare, Inc.*, 469 F. Supp. 3d 431, 441 (E.D. Pa. 2020) (citing 42 U.S.C. § 1396, *et seq.*). “Both federal and state statutes and regulations apply to the state-administered Medicaid programs.” *Id.* (citing 42 U.S.C. § 1396a). “Care providers are paid by the state based on a set of established rates for certain types of care and the federal government reimburses the state for a statutorily determined share of the expenses paid.” *United States ex rel. Schieber v. Holy Redeemer Healthcare Sys., Inc.*, Civ No. 19-12675, 2024 WL 1928357, at *2 (D.N.J. Apr. 30, 2024). Like the Medicare program, entities providing medical services may submit reimbursement claims to Medicaid. (*See* ECF No. 32 ¶ 17.)

3. Medicare and Medicaid Anti-Kickback Statute

The Anti-Kickback statute is a “law aimed at preventing fraud in the context of federal health [] care programs.” *United States ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 664 (W.D. Pa. 2014). In pertinent part, the Anti-Kickback statute prohibits knowingly and willfully offering or paying “any remuneration . . . to any person to induce such person . . . to refer an individual to a person for the furnishing . . . of any item or service for which payment may be made in whole or in part under a Federal health care program.” *United States ex rel. Greenfield v. Medco Health Sol., Inc.*, 880 F.3d 89, 94-95 (3d Cir. 2018) (quoting 42 U.S.C. § 1320a-7b(b)(2)(A)). Further,

⁵ Page numbers for record cites (*i.e.*, “ECF Nos.”) refer to the page numbers stamped by the Court’s e-filing system and not the internal pagination of the parties.

the Anti-Kickback statute “also prohibits ‘knowingly and willfully solicit[ing] or receiv[ing]’ kickbacks ‘in return’ for such conduct. *Id.* (quoting 42 U.S.C. § 1320a-7b(b)(1)(A)).

Courts have found that “the occurrence of kickbacks is . . . common in the context of laboratory tests billed to Medicare.” *United States ex rel. Riedel v. Boston Heart Diagnostics Corp.*, 332 F. Supp. 3d 48, 57 (D.D.C. 2018). In 1994, “the U.S. Department of Health and Human Services, Office of Inspector General (‘OIG’), issued a Special Fraud Alert that addressed laboratory practices that violated the Anti-Kickback Statute, including, but not limited to, ‘routine waiver of Medicare Part B co-payments and deductibles.’” *Id.* at 57-58 (quoting Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65,372, 65,373 (Dec. 19, 1994)).

4. The False Claims Act

The False Claims Act (FCA) was enacted in 1863 “with the principal goal of ‘stopping the massive frauds perpetrated by large [private] contractors during the Civil War.’” *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 781 (2000) (alteration in original) (quoting *United States v. Bornstein*, 423 U.S. 303, 309 (1976)). Despite numerous amendments, the FCA’s “focus remains on those who present or directly induce the submission of false or fraudulent claims.” *Universal Health Servs., Inc. v. United States and Massachusetts ex rel. Escobar*, 579 U.S. 176, 182 (2016). Importantly, however, the FCA “is not ‘an all-purpose antifraud statute,’ . . . or a vehicle for punishing garden-variety breaches of contract or regulatory violations.” *Id.* at 194 (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)).

The FCA “imposes civil liability on any person who presents false or fraudulent claims for payment to the Federal Government.” *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 423 (2023); *United States v. Janssen Biotech, Inc.*, 576 F. Supp. 3d 212, 223 (D.N.J. 2021) (the FCA imposes liability on any person who “(A) knowingly presents, or causes to be

presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or] (C) conspires to commit a violation of subparagraph (A) [or] (B)” (quoting 31 U.S.C. § 3729(a)(1))). “The government may bring a direct suit to recover damages resulting from fraudulent claims or, ‘[a]lternatively, a private plaintiff [known as a relator] may bring a *qui tam* action on behalf of the government to recover losses incurred because of fraudulent claims.’”

United States ex rel. Ascolese v. Shoemaker Constr. Co., 55 F.4th 188, 190 (3d Cir. 2022) (alterations in original) (quoting *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 185 (3d Cir. 2001)); see *Polansky*, 599 U.S. at 423-24 (The FCA “is unusual in authorizing private parties—known as relators—to sue on the Government’s behalf.”). While the injury asserted in a *qui tam* suit “is exclusively to the Government,” *Polansky*, 599 U.S. at 425, “[i]f a *qui tam* suit succeeds, the relator may share in the recovery,” *United States ex rel. DiLello v. Hackensack Meridian Health*, Civ. No. 20-02949, 2022 WL 1284734, at *3 (D.N.J. Apr. 29, 2022).

B. The Parties

Defendant Genesis “owns and operates a clinical testing and diagnostic laboratory providing molecular diagnosis and anatomic pathology solutions, focused on gastrointestinal and respiratory diseases.” (ECF No. 32 ¶ 2.) Its services and tests include molecular pathology diagnostics, anatomical pathology test, cytopathology, tissue pathology, and the fluorescence in situ hybridization (FISH) test. (*Id.* ¶ 8, nn.4-7.) Genesis operates out of its principal office in Oakhurst, New Jersey. (*Id.* ¶ 6.) Defendant Metropolitan, “is a sister company to Defendant Genesis” and “provides billing services t[o] health [] care professionals.” (*Id.* ¶ 13.) Metropolitan “provides full billing services for Genesis.” (*Id.* ¶ 14.) Additionally, Genesis and Metropolitan have similar ownership and “work out of the same building in a different suite.” (*Id.* ¶ 13.)

Relator Amanda Montefinese is employed with Genesis and assists in managing the sales team and training personnel on new products. (*Id.* ¶ 4.⁶) She previously worked for Metropolitan for approximately ten months. (*Id.*) Relator Marla Jensen was employed by Genesis from July 2018 until July 2020 as a client service supervisor. (*Id.* ¶ 5.) Her duties involved being the point of contact for the sales team, handling onboarding of all new clients, preparing reports for the sales team and management, and ensuring laboratory reports were completed in a timely fashion. (*Id.*)

C. Factual Background

1. Overview

As a clinical testing and diagnostic laboratory, Genesis offers multiple panels⁷ that providers may order, including respiratory, gastrointestinal (GI) pathogen, or diarrhea pathogen panels. (*Id.* ¶ 53.) When providers order panels, Genesis “sales representatives provide ‘kits[]’ to [the] providers that include the testing materials, instructions and requisition [f]orms that must be completed and signed by the ordering physician or licensed provider.” (*Id.*) These kits, for example, contain materials such as collection devices, gloves, and freezer packs, as well as instructions for use and information for purposes of shipping back the kits to Genesis to complete the testing. (*Id.*)

Once a kit is received, Genesis’ technicians “open the kits, review the [r]equisition [f]orms, [and] input[] patient demographics, the ordering provider, the location where the physician works, the tests ordered and insurance information.” (*Id.* ¶¶ 68-70.) From there, Genesis works with

⁶ In their brief, Defendants assert that Montefinese is no longer employed by Genesis. (ECF No. 44-1 at 9 n.1.)

⁷ “Laboratory panels or chemistry panels are groups of tests that are ordered together for a specified member on a specified day.” (ECF No. 32 ¶ 5 n.2.)

Metropolitan for purposes of billing Medicare and Medicaid for the services provided. (*Id.* ¶¶ 13-14.)

The SAC alleges that there is “[l]ittle or no training . . . offered or provided to lab personnel” when it comes to reviewing the kits. (*Id.* ¶ 69.) Additionally, “[t]here are no formal written procedures and little or no quality control.” (*Id.*)

2. The Genesis Panels and Requisition Forms

Genesis offers two types of respiratory panels to providers: (1) the Focused Upper Respiratory Panel, and (2) the Expanded (Comprehensive) Panel RP2. (*Id.* ¶¶ 57-58.) The Focused Upper Respiratory Panel tests for COVID-19 and “three other tests, . . . Influenza A and B and RSV.” (*Id.* ¶ 57.) The tests may be bundled together or may be ordered separately if “any of the ‘bundle’ is not medically necessary.” (*Id.*) The RP2 Panel includes twenty-one tests for “commonly associated respiratory pathogens.” (*Id.* ¶ 58.) These tests may also be ordered separately. (*Id.*) “Up until February 15, 2020 (before the onset of COVID-19), [the] Genesis Requisition Form offered only Focused Viral Panel and RP2 Panels.” (*Id.* ¶ 60.)

In addition to respiratory panels, Genesis offers GI panels, diarrhea pathogen panels (DPP), and intestinal and viral panels. (*See id.* ¶¶ 61-64.) As to the DPP, this Panel “is an integrated test for simultaneous detection of 22 of the most commonly diagnosed diarrhea pathogens in humans.” (*Id.* ¶ 61.) The Comprehensive GI Panel includes the DPP “plus an assortment of sixteen (16) additional stool diagnostic tests.” (*Id.* ¶ 62.) In addition to DPP and the Comprehensive GI Panel, Genesis offers three separate panels that test for intestinal viruses and bacteria. (*Id.* ¶ 63.)

Relators assert that the DPP and the Comprehensive GI Panel have “twenty-two different tests that cannot be offered individually,” (*id.* ¶ 64), and that the RP2 Panel has “twenty-one tests that cannot be individually ordered,”⁸ (*id.* ¶ 65).

3. *The Alleged Fraud*

a. “Medically Unnecessary” Testing

Relators allege that through February 15, 2020, Defendants were submitting claims for laboratory services that were “medically unnecessary.” (*Id.* ¶ 3.) Defendants were carrying out this purportedly fraudulent scheme by: (1) “routinely bundling unnecessary” laboratory tests with other laboratory tests that were medically necessary; (2) “furnishing services and lab tests in excess of the patient’s needs . . . where . . . only some tests could be considered reasonable and medically necessary”; (3) “performing lab tests in excess of what was requested by the ordering [p]rovider”; (4) billing for duplicative tests; and (5) “using non-compliant [l]aboratory [r]equisition [f]orms to promote and market the medically unnecessary tests and panels.” (*Id.* ¶¶ 3, 30, 32.)

According to Relators, “Genesis encourages and promotes providers to order . . . medically unnecessary tests[] through marketing materials and test panels” on Genesis’ requisition forms. (*Id.* ¶ 32.) Relators claim that Genesis “has an independent duty to ensure the medical necessity of the tests it performs,” making “blind deference to the ordering physician” impermissible when the laboratory is being reimbursed by the Government. (*Id.*) Relators reference a sample respiratory testing form “used by Genesis up until February 15, 2020,” and assert that “Genesis does not require on its respiratory lab requisition form a statement of certification of medical necessity from the provider.” (*Id.* ¶ 33 (citing ECF No. 32-1, Exh. A).) As a result, Relators

⁸ The SAC appears to have contradictory language regarding whether or not providers may order individual RP2 tests. (*Compare* ECF No. 32 ¶ 58 (indicating that RP2 Panel tests can be ordered separately) *with* ¶ 65 (indicating that RP2 Panel tests cannot be ordered separately).)

contend that “Genesis cannot claim reliance on the clinical judgment of the provider or physician requesting the tests.” (ECF No. 32 ¶ 33.) Relators also assert that “Genesis has an obligation to establish that the tests for which it seeks government reimbursement are medically necessary because when it submits the CMS-1500 form, it certifies that the tests performed were medically necessary.” (ECF No. 32 ¶ 35.)

Relators further allege that Defendants have failed to comply with the OIG Guidelines, which has ostensibly contributed to the alleged fraud. (*Id.* ¶¶ 39-47, 54-55.) In particular, and in accordance with OIG Guidelines, “Defendants do not use a standardized common uniform requisition form that emphasizes physician choice and encourage[s] doctors to order, to the extent possible, only those tests that they believe are appropriate for each patient.” (*Id.* ¶ 43.) Rather, “Genesis performs laboratory services using a requisition form which caused physicians to illegally bundle profiles, thus forcing physicians to order laboratory testing that was not medically necessary[,]” and “[t]he requisition form was formatted in a manner that encouraged physicians to order bundles of tests and thus include tests that were medically unnecessary.” (*Id.* ¶ 44.)

Relators assert that because Defendants failed to comply with the OIG Guidelines, “approximately 20% - 25% of the [r]eququisition [f]orms do not clearly indicate, if at all, what tests the provider is seeking or whether the tests that are being requested are medically necessary.” (ECF No. 32 ¶ 71.) Further, “[t]he compliance problems that occur with the [r]eququisition [f]orms that routinely arrive at Genesis include (a) orders that include a designated [p]anel, and the individual tests that make up that panel, (b) unsigned [r]eququisition [f]orms, and (c) no specific tests being identified.” (*Id.* ¶ 72.) Relators allege that Genesis fails to contact the providers when requisition forms are incomplete or contradictory, and as a result “take[s] the opportunity to order the maximum number of tests, whether medically necessary or not.” (*Id.* ¶ 73.) Further, because

Genesis does not have any quality control measures in place, panels are sometimes “being performed on . . . patient[s] with no symptoms.” (*Id.* ¶ 74.)

b. Waiving Copayments

Relators allege that Defendants violated the Anti-Kickback statute by “routinely waiving the coinsurance . . . (co-pays and other cost sharing requirements)” required by Medicare and Medicaid to “induce[] providers to use their molecular and pathology lab and services.” (ECF No. 32 ¶ 3.) Further, “Defendants, by [their] submission of claims for reimbursement falsely certified compliance with the [Anti-Kickback statute], rendering such claims for reimbursement false.” (*Id.*)

Defendants were carrying out this fraudulent scheme by: (1) “writing off patients’ balances”; (2) “provid[ing] assurances to health care providers that their customers or patients will no[t] receive a bill from Defendants”; (3) “mak[ing] no effort to collect payments that would otherwise be due”; and (4) “advising patients directly that they will not be billed despite what an Explanation of Benefits (EOB) states.” (*Id.* ¶ 85.) The SAC contains a chart outlining examples of patient accounts where amounts were written off without any collection efforts or determination that charity care was appropriate. (*Id.* ¶ 86.) Relators assert that all of the amounts listed in the final column of the chart (Patient Responsibility) were not marked with any sort of information justifying the write-off. (*Id.* ¶ 87.)

Relators allege that Defendants had a “write[-]off” policy in place from October 28, 2019, through November 1, 2019. (*Id.* ¶ 88.) As an example of this policy, the SAC recounts an event where a sales representative questioned the write[-]off policy and was “assured that . . . patients would not receive a bill.” (*Id.*) The SAC provides another example of the President and Chief

Executive Officer of Genesis speaking to sales staff about being cautious in discussing the write-off policy. (*Id.* ¶ 89.)

D. Procedural History

On October 28, 2020, Relators filed their original Complaint under seal. (ECF No. 1.) Over two years later, Relators filed their First Amended Complaint. (ECF No. 15.) On January 22, 2024, the United States filed a notice of election to decline intervention. (ECF No. 22.) On February 1, 2024, California, Florida, Illinois, New Jersey, New York, Rhode Island, Texas, Maryland,⁹ Connecticut, Massachusetts, and Virginia also filed a notice of election to decline intervention. (ECF No. 24.)

On March 27, 2024, Relators filed their SAC. (ECF No. 32.) Relators assert twelve counts against Defendants for violations of the FCA, 31 U.S.C. § 3729(a)(1)(A)-(C), (Counts One through Three), and violations of various state FCA counterparts (Counts Four through Twelve). (ECF No. 32 at 35-42.)

II. LEGAL STANDARD

On a motion to dismiss for failure to state a claim, courts “accept the factual allegations in the complaint as true, draw all reasonable inferences in favor of the plaintiff, and assess whether the complaint and the exhibits attached to it ‘contain enough facts to state a claim to relief that is plausible on its face.’” *Wilson v. USI Ins. Serv. LLC*, 57 F.4th 131, 140 (3d Cir. 2023) (quoting *Watters v. Bd. of Sch. Dir. of City of Scranton*, 975 F.3d 406, 412 (3d Cir. 2020)). “A claim is

⁹ Because Maryland declined to intervene, the Court dismissed all claims asserted on behalf of Maryland without prejudice in accordance with the Maryland False Health Claims Act, Md. Code Ann., Health Gen, § 2-604(a)(7). (ECF No. 25 ¶ 5.) *See also Groat I*, 255 F. Supp. 3d at 20 n.5 (noting that Maryland’s false claims statute only allows an action to proceed if the state intervenes).

facially plausible ‘when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.’” *Clark v. Coupe*, 55 F.4th 167, 178 (3d Cir. 2022) (quoting *Mammana v. Fed. Bureau of Prisons*, 934 F.3d 368, 372 (3d Cir. 2019)). When assessing the factual allegations in a complaint, courts “disregard legal conclusions and recitals of the elements of a cause of action that are supported only by mere conclusory statements.” *Wilson*, 57 F.4th at 140 (citing *Oakwood Lab’ys LLC v. Thanoo*, 999 F.3d 892, 903 (3d Cir. 2021)). The defendant bringing a Rule 12(b)(6) motion bears the burden of “showing that a complaint fails to state a claim.” *In re Plavix Mktg., Sales Pracs. & Prod. Liab. Litig. (No. II)*, 974 F.3d 228, 231 (3d Cir. 2020) (citing *Davis*, 824 F.3d at 349).

When claims sound in fraud, plaintiffs “must satisfy the heightened pleading standards of Federal Rule of Civil Procedure 9(b).” *Burns v. Stratos*, 2023 WL 4014474, at *2 n.3 (3d Cir. June 15, 2023) (citing *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007)); *see also* Fed. R. Civ. P. 9(b) (“In alleging fraud . . . , a party must state with particularity the circumstances constituting fraud . . . ”). This ordinarily requires “[a] plaintiff alleging fraud . . . [to] support its allegations ‘with all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue.’” *U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016) (quoting *In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002)); *accord Frederico*, 507 F.3d at 200 (“To satisfy this standard, the plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation.”). “Rule 9(b)’s ‘normally rigorous particularity rule has been relaxed somewhat where the factual information is particularly within the defendant’s knowledge or control.’ But even if a relaxed application of Rule 9(b) were warranted . . . , [a]

plaintiff] would still need to allege facts demonstrating that his [or her] fraud claims are plausible.” *Tripati v. Wexford Health Sources Inc.*, 2022 WL 17690156, at *2 n.3 (3d Cir. Dec. 15, 2022) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997)); *In re Rockefeller Ctr. Properties*, 311 F.3d at 216 (“[C]ourts should be ‘sensitive’ to situations in which ‘sophisticated defrauders’ may ‘successfully conceal the details of their fraud. . . .’ Where it can be shown that the requisite factual information is peculiarly within the defendant’s knowledge or control, the rigid requirements of Rule 9(b) may be relaxed.” (quoting *In re Burlington*, 114 F.3d at 1418)).

An FCA complaint must meet Rule 9(b)’s heightened pleading standard. *United States ex rel. Petras v. Simparel, Inc.*, 857 F.3d 497, 502 (3d Cir. 2017). “[U]nder this pleading standard, a plaintiff need not identify a specific claim for payment.” *Janssen*, 576 F. Supp. 3d at 223 (citing *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156 (3d Cir. 2014)). Rather, a plaintiff need only provide “particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.” *Foglia*, 754 F.3d 153, 157-58 (3d Cir. 2014). However, “[d]escribing a mere opportunity for fraud will not suffice.” *Id.* at 158. “Allegations of ‘facts that could plausibly have either a legal or illegal explanation’ fall short of Rule 9(b)’s burden because ‘the possibility of a legitimate explanation undermines’ an inference that false claims were submitted.” *United States v. Bracco USA, Inc.*, Civ. No. 20-8719, 2024 WL 1161384, at *3 (D.N.J. Mar. 14, 2024) (quoting *United States v. Omnicare, Inc.*, 903 F.3d 78, 92 (3d Cir. 2018)).

III. DISCUSSION

Relators assert that Defendants violated three specific provisions of the FCA: presenting or causing to be presented a false claim under 31 U.S.C. § 3729(a)(1)(A); making or using a false

statement in connection with a claim under 31 U.S.C. § 3729(a)(1)(B), and conspiracy under 31 U.S.C. § 3729(a)(1)(C) (Counts One through Three). (ECF No. 32 at 35-42.)

As to Relators' medically unnecessary testing assertion, Defendants argue that: (1) Relators "cannot base their FCA claim on non-binding and voluntary guidance" by the OIG; and (2) Relators "have failed to plead with particularity that Defendants submitted claims for medically unnecessary tests." (ECF No. 44-1 at 16-29.) As to the Anti-Kickback violations, Defendants argue that Relators "have not pled an [Anti-Kickback statute] violation with particularity" because Relators have not pled remuneration or inducement. (*Id.* at 29-36.) Finally, Defendants argue that the state FCA claims must be dismissed because Relators have "not made separate allegations pertaining to the state law claims, and thus each state law claim rests on the exact same factual allegations and exact same [] theory as . . . [the] FCA claims." (*Id.* at 37.) The Court will address each of Defendants' arguments in turn.

A. Relators' Claims under the FCA

1. Presenting False Claims & Making/Using False Statements under 31 U.S.C. § 3729(a)(1)(A) and (a)(1)(B)

A violation of the FCA occurs when a person "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). A violation also occurs when a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* § 3729(a)(1)(B). "The only difference between subsections (A) and (B) is that subsection (B) contains an additional element—use of a false record or statement." *United States ex rel. All State Ins. Co. v. Phoenix Toxicology and Lab Serv., LLC*, Civ No. 22-6303, 2024 WL 2785396, at *6 (D.N.J. May 30, 2024) (citing *United States ex rel. Zwirn v. ADT Sec. Servs., Inc.*, Civ. No. 10-2639, 2014 WL 2932846, at *5 (D.N.J. June 30, 2014)).

The United States Court of Appeals for the Third Circuit has indicated that a FCA violation “includes four elements: falsity, causation, knowledge, and materiality.” *United States ex rel. v. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017) (citing *Escobar*, 579 U.S. at 176, and *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 304-05 (3d Cir. 2011)); *United States v. Care Alt.*, 81 F.4th 361, 366-67 (3d Cir. 2023) (same).

“A false or fraudulent claim may be either factually false or legally false.”¹⁰ *United States ex rel. Greenfield v. Medco Health Sol., Inc.*, 880 F.3d 89, 94 (3d Cir. 2018). “A claim is factually false when the claimant misrepresents what goods or services . . . it provided to the Government,” and “a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment.” *Wilkins*, 659 F.3d at 304. A review of the SAC indicates that Relators rely on a legally false theory of liability. (See, e.g., ECF No. 32 ¶¶ 3, 95, 99-101.)

Within legal falsity lies “two subsidiary theories: express false certification and implied false certification.” *Janssen*, 576 F. Supp. 3d at 227. “Under the ‘express false certification’ theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds.” *Wilkins*, 659 F.3d at 305 (quoting *Rodriguez v. Our Lady of Lourdes Med. Center*, 552 F.3d 297, 303 (3d Cir. 2008)). Under the “implied false certification” theory,

¹⁰ Courts in the Third Circuit “have recognized a narrow, third category of false claims obtained by ‘fraud-in-the-inducement.’” *In re Plavix Mktg., Sales Pracs. & Prod. Liab. Litig. (No. II)*, 332 F. Supp. 3d 927, 939 (D.N.J. June 27, 2017). “Courts have employed this theory to establish FCA liability ‘for each claim submitted to the government under a contract which was procured by fraud, even in the absence of evidence that the claims were fraudulent in themselves.’” *Janssen*, 576 F. Supp. 3d at 228 (quoting *United States ex rel. Thomas v. Siemens AG*, 593 F. App’x 139, 143 (3d Cir. 2014)). Based on a review of the SAC, Relators do not assert an FCA violation under the fraud-in-the-inducement theory.

an entity is liable if it “seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment.” *Id.*; *see Escobar*, 579 U.S. at 181 (“[L]iability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant’s noncompliance with a statutory, regulatory, or contractual requirement. In these circumstances, liability may attach if the omission renders those representations misleading.”).

Here, Relators appear to pursue both theories—express and implied. (*See* ECF No. 32 ¶ 35 (alleging that when Genesis submits the CMS-1500 form it certifies that the tests performed were medically necessary); ¶ 38 (alleging that separate from an express certification, the Medicare statute expressly provides that services will not be reimbursed unless they are “reasonable and necessary”); ¶ 83 (alleging that the Provider agreement requires compliance with the Anti-Kickback statute); ¶¶ 99-101 (setting forth allegations regarding “Defendants’ Implied and Express Certifications”).

a. Medically Unnecessary Testing

As a threshold matter, the Court is not persuaded by Defendants’ argument that the SAC should be dismissed because the Relators “base their FCA claim on non-binding and voluntary guidance.” (ECF No. 44-1 at 16-29.) Defendants are correct that the OIG Guidance referenced throughout the SAC is voluntary, and therefore not binding on laboratories. *See* Publication of the OIG Model Compliance Plan for Clinical Laboratories, 62 FR 9435-01, 1997 WL 84752 (Mar. 3, 1997) (“Adoption of the clinical laboratory model compliance plan . . . will be voluntary.”) (OIG Model Compliance Plan for Clinical Laboratories I); Publication of OIG Compliance Program Guidance for Clinical Laboratories, 63 FR 45076-03, 1998 WL 517789 (Aug. 24, 1998) (OIG Model Compliance Plan for Clinical Laboratories II). However, while the SAC relies extensively

on Defendants' failure to abide by the nonbinding OIG Guidance, the SAC also makes clear that the alleged fraud stems from Defendants' failure to abide by the Medicare statute and regulations, specifically the requirement that "no payment may be made under [Medicare] part A or part B for any expenses incurred for items or services . . . which[] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 410.32(d)(3)(ii). (See ECF No. 32 ¶¶ 30-31, 34-36 (alleging that Defendants: (1) ignored OIG standards which resulted in Defendants submitting claims that were in excess of the patient's needs, (2) furnished a battery of diagnostic tests where only some were needed, and (3) misrepresented and/or disregarded the diagnosis and clinical indications to justify the services in violation of Medicare regulation 42 C.F.R. § 410.32. Further alleging that Defendants, as the entity submitting the claim for payment and pursuant to the CMS-1500 form, certifies that the tests performed were medically necessary pursuant to 42 U.S.C. § 1395y and 42 C.F.R. § 410.32). See also *United States ex rel. Allstate Ins. Co. v. Phoenix Toxicology & Lab Servs., LLC*, Civ. No. 22-6303, 2024 WL 2785396, at *9 (D.N.J. May 30, 2024) (recognizing that a laboratory should maintain an effective compliance program to fulfill its "legal duty to ensure that it is not submitting false or incorrect claims to Government and private payors"). Thus, the Court will not dismiss Relators' SAC on this basis alone.

Next, Defendants argue that the SAC should be dismissed because Relators "have failed to plead basic facts supporting a lack of medical necessity, much less to plead those facts with particularity." (ECF No. 44-1 at 23.) Specifically, Defendants argue that Relators never state "when" this scheme occurred or "how" providers choosing from a menu of panels causes Defendants to submit medically unnecessary tests. *Id.*

In response to Defendants' arguments, Relators cite to various portions of the SAC. (*See, e.g.*, ECF No. 47 at 33-36 (citing ECF No. 32 ¶¶ 4-5, 33-38, 40, 42-46, 54-74, 82, 86-91).) As to "when" the fraud occurred, the SAC alleges that through February 15, 2020, Defendants were submitting claims for laboratory services that were "medically unnecessary." (*See, e.g.*, ECF No. 32 ¶ 3.) The SAC also provides dates for when the Relators were employed at Genesis and Metropolitan, (*id.* ¶¶ 4-5), as well as scattered dates (between September and October 2019) on the requisition forms that are attached as exhibits to the SAC, (*see, e.g.*, ECF No. 32-1 at 11-27).

As to "how" the alleged fraud occurred, Relators claim that Defendants used "preprinted test requisition forms,"¹¹ which bundled tests into panels, allegedly resulting in duplicative and medically unnecessary testing, and that had Defendants implemented compliance procedures, such as those outlined in the voluntary OIG Guidelines, this medically unnecessary testing would presumably not have occurred. (*See* ECF No. 32 ¶¶ 54-74.) Relators assert that Defendants falsely certified to the Government that the tests were medically necessary based on an improper reliance on the providers' certification of medical necessity as outlined in the requisition forms. (*Id.* ¶¶ 33-38; ECF No. 47 at 34-36.)

Accepting the factual allegations in the SAC as true and drawing all reasonable inferences in favor of Relators, the Court finds that Relators have failed to satisfy the Rule 9(b) pleading requirement as to "when" and "how" the alleged fraud occurred.¹² As to "when" the alleged fraud

¹¹ The allegations in the SAC center around the GI testing requisition forms as opposed to the respiratory testing forms. Indeed, the only sample requisition forms filled out by providers are the GI related requisition forms not the respiratory requisition forms. (*See* ECF No. 32-1 at 11-27.)

¹² The Court finds that the SAC provides the "essential factual background" as to "who" is alleged to have perpetrated the fraudulent scheme (Defendants); "where" the scheme took place (Genesis' principal location in Oakhurst, New Jersey); and "what" the alleged scheme was

occurred, it is not enough for Relators to assert that the fraud occurred “through February 15, 2020,” without alleging any timeframe as to when the fraud began or for how long the fraud took place. Nor is it sufficient to intersperse other timeframes in the SAC, such as Relators’ dates of employment (*see, e.g.*, ECF No. 32 ¶¶ 4-5), without specifying that the fraud occurred during such timeframe. *See United States ex rel. Simmons v. New Horizons Cmty. Charter Sch.*, Civ. No. 20-00196, 2020 WL 6305513, at *1, 3 (D.N.J. Oct. 28, 2020) (dismissing FCA complaint because, among other deficiencies, the “[p]laintiff [did] not indicate, even by rough approximation, when the alleged fraud took place or for how long,” and noting that the complaint listed dates of employment, dates of complaints, and the date of termination); *United States ex rel. Knisely v. Cintas Corp., Inc.*, 298 F.R.D. 229, 240 (E.D. Pa. 2014) (dismissing FCA claim because, among other things, it “f[e]ll far short of [the] newspaper-reporting standard: [the relator] d[id] not allege . . . when or how the fraudulent billing occurred . . .”); *United States ex rel. Hilliard v. Hardin House Inc.*, 2020 WL 362796, at *2 (N.D. Ill. Jan. 22, 2020) (finding that the FCA claim was deficient because “the [s]econd [a]mended [c]omplaint only narrow[ed] the window to a nine-year period reaching back to ‘at least 2011’”). Plaintiff’s sole allegation that the fraud occurred “through February 15, 2020” is simply too indefinite, and therefore falls short of meeting the pleading requirements for “when” the alleged fraud took place.

The SAC also falls short of alleging “how” Genesis’ pre-printed requisition forms and test panels lead to the submission of false claims. *See Foglia*, 754 F.3d at 157-58. To survive a motion to dismiss, a relator must allege facts demonstrating falsity beyond the use of the test panels and pre-printed requisition forms. *See, e.g.*, *Groat II*, 296 F. Supp. 3d at 165 (declining to dismiss

(Defendants submitting CMS 1500 forms to Medicare for reimbursement of “medically unnecessary” testing). (*See, e.g.*, ECF No. 47 at 33 (citing ECF No. 32 ¶¶ 28, 30, 34, 35, 54-76).)

FCA claim because relators pled facts that the defendant encouraged providers to order medically unnecessary tests through marketing materials and test panels on pre-printed requisition forms that allegedly contained false marketing statements regarding the medical necessity of the tests and their ability to predict cardiac risk); *United States ex rel. Schaefer v. Family Med. Ctrs. of S.C., LLC*, 2016 WL 6601017, at *3-4 (D.S.C. Nov. 8, 2016) (denying a motion to dismiss FCA claims because the complaint “allege[d] that [the] [d]efendants created and utilized custom disease-oriented panels that included more diagnostic tests than typical for screening or routine testing,” and noting that “[t]he United States allege[d] that [the] [d]efendants stressed to the physicians . . . to utilize the laboratory panels designed by [the] [d]efendants, regardless of whether all components of the panel were medically necessary”); *United States ex rel. Lutz v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 497 (D.S.C. 2016) (declining to dismiss FCA claim based on alleged submissions of medically unnecessary tests because the defendants “encouraged physicians to order tests that were medically unnecessary” such as “unnecessary genetic testing on patient blood samples held [in storage by one of the defendant’s laboratories]”); *United States ex rel. Downy v. Corning, Inc.*, 118 F. Supp. 2d 1160, 1172 (D.N.M. 2000) (declining to dismiss FCA claim because the complaint alleged that “by using deceptive test order forms and by disseminating deceptive information concerning the necessity of performing both [medical] tests, Defendants induced physicians to order many medically unnecessary tests and then charged the costs of those tests to the government”). Here, the SAC contains no such allegations.

The SAC includes one allegation that Genesis uses marketing materials to encourage or promote unnecessary medical testing. (ECF No. 32 ¶ 32; ECF No. 44-1 at 28.) However, this sole allegation is too conclusory. The SAC fails to identify or explain what these alleged “marketing materials” are or how Genesis used the marketing materials to “encourage[] and promote[]

providers to order . . . medically unnecessary tests.” (See ECF No. 32 ¶ 32.) *Cf. Groat II*, 296 F. Supp. 3d at 165 (noting that the relators had sufficiently alleged that the defendants “engaged in a scheme to encourage non-cardiology physicians to order medically unnecessary tests through a false marketing campaign and pre-printed test requisition forms” by allegedly advertising false statements about the ability of the tests to predict cardiac risk); *United States ex rel. Wallace v. Exactech, Inc.*, 2020 WL 4500493, at *18 (N.D. Al. Aug. 5, 2020) (finding that the relators sufficiently alleged how the marketing materials were false because the complaint claimed the marketing materials contained incorrect or inaccurate information).

At most, Relators’ allegations indicate that Defendants’ pre-printed requisition forms and test panels have the potential of causing physicians to order duplicative testing. However, the mere opportunity or potential for fraud will not suffice. *Foglia*, 754 F.3d at 158. The Court finds the rulings in *United States ex rel. Allen v. Alere Home Monitoring, Inc.*, 334 F. Supp. 3d 349 (D. Mass. 2018) and *United States ex rel. Allstate Insurance Company v. Phoenix Toxicology & Lab Services, LLC*, 2024 WL 2785396 instructive on this point.

In *Allen*, the relator brought a *qui tam* action against eight defendants pertaining to Medicare reimbursements for at-home blood testing kits. 334 F. Supp. 3d at 352. The relator alleged that the defendants violated the FCA by “requiring two to four monthly tests as a precondition to providing kits,” which “induce[d] doctors to order medically unnecessary tests.” *Id.* Specifically, the relator asserted that the defendants: (1) “coerce[d] patients and their doctors to agree to weekly testing (the maximum for which Medicare will reimburse) or to two tests per month without regard to whether those frequencies [were] medically necessary”; (2) “pressure[d] doctors chiefly by removing less-frequent testing options from their pre-printed enrollment forms”; and (3) “encourage[d] the ordering of more tests than necessary through marketing material[s]” by

referencing “studies intended to lead patients and doctors to believe that more-frequent testing will lead to better health outcomes.” *Id.* at 353. The relator claimed that “all of the Defendants’ pre-printed enrollment forms are necessarily false because they all provide for particular testing frequencies (*e.g.*, two tests per month, or four tests per month),” and “[i]n the [r]elator’s view, these limited frequency options induce doctors to increase the frequency with which patients test.” *Id.* at 356.

In dismissing the relator’s claims, the court found that the relator failed to sufficiently plead the falsity element because “all tests at issue . . . were approved by a treating physician, and, even according to the complaint, many were medically necessary.” *Id.* at 358. Further, the court emphasized that “[t]he physicians’ intervening medical judgment is the main impediment to [the] [r]elator’s theory,” and that standing alone, “the form does not permit one to distinguish between a claim that involved genuine medical judgment and a claim that was medically unnecessary.” *Id.* at 359. As a result, the court concluded that “the forms, by themselves, may create a possibility of fraud by pressuring doctors into prescribing medically unnecessary tests to give their patients the convenience of at-home testing. But they do not give rise to a ‘strong inference’ that false claims were actually submitted.” *Id.*

In *Allstate*, a recent decision from this District, a relator brought a *qui tam* action against the defendants for allegedly “duplicative, excessive, and medically unnecessary urine drug testing (“UDT”).” 2024 WL 2785396, at *1. The relator alleged that the defendants violated the FCA through the “Duplicative Presumptive UDT Scheme” (DP UDT). *Id.* at 2-3. As part of the DP UDT scheme, referring providers performed a “presumptive” UDT, also known as a point-of-care test, at their offices to determine whether a patient’s urine tested positive or negative for the presence of drugs. *Id.* The relator alleged that the defendant’s “requisition form solicit[ed] from

the provider the result of the screening test when the provider refer[red] a patient for UDT, and whatever the result of the screening test—positive or negative—[the defendant] allegedly performed a second test on the same urine sample.” *Id.* The relator further asserted that the second test was “unnecessarily duplicative and contrary to CMS regulations where the referring provider’s screening test rendered a negative result” and that the defendant “encouraged providers to conduct point-of-care screening tests and to refer patients for duplicative testing by soliciting the result of the screening on its requisition form.” *Id.*

In denying the defendant’s motion to dismiss, the court determined that the relator sufficiently alleged enough facts to establish the falsity element as to the DP UDT scheme. *Id.* at 9. The court reasoned that the relator “sufficiently alleged that [the defendant] engaged in a scheme to conduct duplicative presumptive testing without regard to medical necessity and . . . encourage[d] physicians to order additional screening tests as a matter of course.” *Id.* Further, the court found that the defendants’ “contrary inference that such tests were reasonable and legitimate because ordering providers determined that they were necessary [was] insufficient to defeat the inference alleged” by the relator. *Id.*

Here, like in *Allen* and *Allstate*, the treating providers certified that the laboratory testing that was ordered was medically necessary. The pre-printed requisition forms attached as exhibits to the SAC include the following language: “It is the provider’s responsibility to order tests that are medically necessary and in the best interest of the patient.” (ECF No. 32-1, Ex. A.) And some of the requisition forms attached to the SAC (*id.* Exs. B-C) include the following additional language: “This test is medically necessary for the diagnosis or detection of disease, illness, impairment, symptom, syndrome or disorder. The results will determine my patient’s medical

management and treatment decisions. The person listed as the order provider is authorized by law to order the test(s) requested herein.” (*Id.*)

Contrary to Relators’ allegations, a laboratory “is permitted to rely on the ordering physician’s determination that the laboratory tests billed to Medicare are medically necessary,” *Groat II*, 296 F. Supp. 3d at 160, and the laboratory is not required “to make an independent determination of medical necessity” when submitting a claim for reimbursement using the CMS 1500 form, *Allstate*, 2024 WL 2785396, at *9. However, reliance on a provider’s certification of medical necessity “is not without qualification.” *Id.* As the Court in *Allstate* recognized, “[t]he ‘tension’ between Medicare’s statutory requirement of medical necessity applicable to laboratories . . . and physicians’ responsibility for determining medical necessity, must yield to a reasonable degree of due diligence on the laboratory’s part.” *Id.* (internal citations omitted).

Even if the Court were to set aside the physician certifications, Relators have not alleged any additional facts, like in *Allstate*, for the Court to infer falsity based on medically unnecessary testing. Relators do not allege that the tests were medically unnecessary based on the nature of the tests. *See Allstate*, 2024 WL 2785396, at *1-3, 9 (holding that falsity could be inferred, despite the physician certifications, based on the allegations that the defendant performed a second presumptive test on the same urine sample even though the initial screening test rendered a negative presence of drugs). Nor have Relators alleged that the treating providers were tricked or confused into ordering medically unnecessary tests, that providers were encouraged to order a specific testing regime, or that the tests were medically unnecessary based on medical literature or physician opinions.¹³ *See United States ex rel. Senter v. Quest Diagnostics, Inc.*, 2024 WL

¹³ To the extent that Relators assert that tests were “being performed on . . . patient[s] with no symptoms,” this allegation is too conclusory and unsupported. (ECF No. 32 ¶ 74; ECF No. 44-1 at 27.) The SAC alleges no factual information to support this broad assertion. Rather, the

4297469, at *5 (N.D. Ga. 2024) (granting the motion to dismiss because “the [r]elator . . . provided no factual allegations to indicate that doctors later discovered, or even [] believe[d], that they were tricked or confused into ordering medically unnecessary tests or tests they did not intend to order[,]” or that the tests ordered (and billed) were medically unnecessary based on “medical literature, physician opinions, or the nature of particular tests”).

Indeed, contrary to Relators’ allegations, the requisition forms attached to the SAC indicate that providers have the option of selecting bundled test panels or individual stool testing. (*See* ECF No. 32-1 at 1-27) (noting that providers have the option of selecting: (1) the DPP testing only; (2) the Comprehensive GI panel, which includes the DPP pathogen testing plus several additional stool diagnostic tests; or (3) a combination of the DPP pathogen testing and the additional stool testing). The exhibits also clearly illustrate which individual tests are included in the different panels. (*Id.*) *See Alonzo v. Fresco Beverages US, Inc.*, Civ. No. 23-22695, 2024 WL 4349592, at *9 (D.N.J. Sept. 30, 2024) (noting that while a court must, on a Rule 12(b)(6) motion, accept all well-pled factual allegations as true, this requirement “does not apply when the allegations are contradicted by the documents attached to the Complaint upon which its claims are based” (quoting *Nasyrova v. Immunomedics, Inc.*, Civ. No. 14-1269, 2015 WL 4388310, at *3 (D.N.J. July 15, 2015))). And, according to the SAC, Relators acknowledge that some tests were medically necessary. (ECF No. 32 ¶¶ 3, 30, 32.) Therefore, standing alone the test panels and pre-printed requisition forms do not permit one to distinguish between a medically necessary versus unnecessary test. *See Allen*, 334 F. Supp. 3d at 358-59.

exhibits attached to the SAC appear to contradict Relators’ assertion. (*See* ECF No. 32-1 at 11-27 (indicating specific symptoms associated with the patients such as “chronic unexplained diarrhea”). *See Alonzo v. Fresco Beverages US, Inc.*, Civ. No. 23-22695, 2024 WL 4349592, at *9 (D.N.J. Sept. 30, 2024)).

Moreover, the Court finds that Relators have failed to provide any “reliable indicia that lead[s] to a strong inference that claims were actually submitted.” *Foglia*, 754 F.3d at 155-56. Relators have only provided conclusory allegations regarding the submission of fraudulent claims. (See, e.g., ECF No. 32 ¶¶ 3, 9, 20, 28, 30, 35, 75-76.) For example, Relators repeatedly allege that Defendants “knowingly submitted, or caused to submitted, false claims for reimbursement” and that Defendants “treat[ed] and bill[ed]” alleged duplicative testing separately “without even attempting to contact the provider.” (See, e.g., *id.* ¶¶ 3, 76.) While the Court is mindful that, at the pleading stage, a relator is not required to identify a false claim that was in fact submitted, the Court is unable to infer based on the allegations in the SAC that there is a strong inference that claims were actually submitted based on some reliable indicia. *Foglia*, 754 F.3d at 155-56; see *Allstate*, 2024 WL 2785396, at *12 (noting that the relator’s “theory raises a strong inference of fraud on the United States because [the defendant] is engaged exclusively in UDT, depends almost entirely on three New Jersey providers for referrals, and has [been] reimbursed a substantially larger sum from the federal government than [the relator] for similar UDT claims”); see also *Allen*, 334 F. Supp. 3d at 358-59 (noting that “the forms, by themselves, may create a possibility of fraud by pressuring doctors into prescribing medically unnecessary tests to give their patients the convenience of at-home testing. But they do not give rise to a ‘strong inference’ that false claims were actually submitted.”)

Thus, for the foregoing reasons, Relators have failed to plead with specificity the falsity element required for their FCA claims to proceed based on the medically unnecessary testing theory.¹⁴

¹⁴ The SAC does not assert facts to suggest that the requisite factual information is peculiarly within Defendants’ knowledge or control to apply a relaxed pleading standard. See *In re Rockefeller Ctr. Properties*, 311 F.3d at 216. Even if the SAC did assert facts suggesting that the

b. Anti-Kickback Violations¹⁵

To state a violation of the Anti-Kickback statute, Relators must plead that Defendants (1) “knowingly and willfully”; (2) “solicit[ed] or receive[d] any remuneration”; (3) “in return for referring an individual to a person for the furnishing . . . of any item or service for which payment may be made in whole or in part under a Federal health care program.” *United States ex rel. Perri v. Novartis Pharm. Corp.*, Civ. No. 15-6547, 2019 WL 6880006, at *10 (D.N.J. Feb. 21, 2019) (quoting *United States v. Goldman*, 607 F. App’x 171, 173-74 (3d Cir. 2015)). “The submission of a Medicare claim in violation of [the Anti-Kickback statute] will establish a ‘legally false’ claim under the FCA.” *United States ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 665 (W.D. Pa. 2014).

In response to Relators’ allegations that Defendants waiver of copayments constitutes a kickback, Defendants argue that: (1) “Relators have not identified any instances where Defendants impermissibly waived a copay”; and (2) “to the extent Relators do allege that any copays were waived, they fail to plead ‘inducement’ as required by the [statute]. . . .” (ECF No. 44-1 at 30.)

Relators “acknowledge[] that medically necessary clinical diagnostic tests are generally not subject to specific test coinsurance or deductibles.” (ECF No. 47 at 11, 19; *see* ECF No. 32 ¶¶ 15, 48.) However, Relators assert that some pathology billing is subject to the Physician Fee Schedule which has a 20% coinsurance and annual deductible. (ECF No. 47 at 11, 19.) Further,

requisite factual information was peculiarly within Defendants’ knowledge or control, because Relators sue as “insiders,” *i.e.*, current and former employees, this is not a case where the pleading requirements should be relaxed. *See United States ex rel. Perri v. Novartis Pharm. Corp.*, Civ. No. 15-6547, 2019 WL 6880006, at *2, 17 (D.N.J. Feb. 21, 2019) (rejecting the relator’s argument that the heightened pleading standard associated with FCA claims should have been relaxed because relator was an employee, *i.e.*, “insider”, of one of the defendants).

¹⁵ A violation of the Anti-Kickback statute does not create a private right of action, but rather may give rise to an independent FCA claim. *See Bracco*, 2022 WL 17959578, at *7.

the SAC “points out that defendants do cytopathology, tissue pathology, and FISH [tests],” and that the regulations “proffered by Defendant are silent as to these pathology services.” (*Id.* at 19-20.) Relators also assert that the “write-off” policy discussed at a particular sales meeting and the virtual sales call sufficiently shows inducement. (*Id.* at 20-21, 36.)

First, the Court agrees with Defendants that “[c]o-payments and deductibles do not apply to services paid under the Medicare clinical laboratory fee schedule,” and therefore Relators have failed to plead remuneration. *See* Processing Manual § 20.3; *see PCTLs, LLC*, 2023 WL 6388328, at *5 (quoting CMS, Clinical Laboratory Fee Schedule (Jan. 2, 2020), perma.cc/Q282-YW5L). Because the tests at issue—respiratory and GI related—are clinical laboratory tests, they are not subject to copayments. To the extent Relators assert that copayments do apply because Defendants offer “cytopathology, tissue pathology, and FISH” tests, and even accepting those allegations as true, the SAC fails to provide more than one cursory reference to those tests. (*See* ECF No. 32 ¶ 8.) Additionally, the exhibits attached to the SAC do not appear to suggest that Defendants performed these types of tests—which would be subject to a copayment and annual deductible—and then subsequently waived the required payments. (*See* ECF No. 32-1 at 29-55.)

Second, even assuming that copayments and annual deductibles applied to the tests performed by Defendants, Relators have failed to sufficiently plead facts to show inducement. The Anti-Kickback statute focuses on the inducement factor. *See Perri*, 2019 WL 6880006, at *16 (quoting *United States v. Greber*, 760 F.2d 68, 71 (3d Cir. 1985)). As courts in this district have recognized, “[t]he crux of whether the Anti-Kickback Statute [is] violated’ is ‘whether the parties entered [into] business arrangements in exchange for, or to induce, patient referrals.’” *Id.* (quoting *Bartlett*, 39 F. Supp. 3d at 678).

Even accepting the factual allegations in the SAC as true and drawing all reasonable inferences in favor of Relators, the SAC’s allegations pertaining to the write-off policy and the virtual sales call (*see ECF No. 32 ¶¶ 88-89*) do not meet Rule 9(b)’s heightened pleading standard. These assertions fail to demonstrate that Defendants waived copayments with the purpose of inducing referrals from either physicians or patients.¹⁶ *See United States ex rel. O’Bier v. TidalHealth Naticoke, Inc.*, Civ. No. 21-2123, 2022 WL 264554, at *3 (3d Cir. Jan. 28, 2022) (affirming a district court’s dismissal of anti-kickback claim because the relator failed to allege how the alleged incentives worked); *Perri*, 2019 WL 6880006, at *16 (dismissing the FCA claim based on alleged kickbacks because the relator merely provided conclusory and unsupported factual details of an alleged inducement); *United States ex rel. Sharp v. Eastern Ok. Orthopedic Center*, Civ. No. 05-572, 2009 WL 499375, at *25 (N.D. Ok. Feb. 27, 2009) (finding that the relator’s kickback theory of FCA liability failed because the relator did not allege that an orthopedic center provided the waiver for purposes of inducing the patient to purchase services); *United States ex rel. Herbert v. Dizney*, 295 F. App’x 717, 723 (5th Cir. 2008) (finding that relators’ allegations that the defendants “routinely failed to collect . . . co-insurance payments,” and that “Medicaid was routinely billed for the portion not paid by other payers” failed to meet the heightened pleading standards under Rule 9(b)); *but see Riedel*, 332 F. Supp. 3d at 67-68 (finding that the relator sufficiently alleged facts that could implicate the Anti-Kickback statute by asserting that the defendant waived “privately insured patients’ co-payments and deductibles, ‘so long as

¹⁶ Relators’ reliance on *City of Warren and Fire Retirement Sys. v. Prudential Financial, Inc.*, 70 F.4th 668 (3d Cir. 2023) is misplaced. (*See ECF No. 47 at 36.*) Here, Relators’ allegations regarding what was discussed at various meetings fails to provide the same level of particularity as discussed in *City of Warren and Fire Retirement System*. Therefore, the allegations regarding the meetings in the SAC fail to meet Rule 9(b)’s heightened pleading standard.

the physicians sen[t] all of their lipid-related business—especially the highly profitable Medicare business—to [the defendant]”).

Therefore, Relators have failed to sufficiently plead their FCA claims based on the anti-kickback theory.¹⁷

2. Conspiracy under 31 U.S.C. § 3729(a)(1)(C)

The FCA imposes liability on those who “conspire[] to commit a violation” of any acts listed in 31 U.S.C. § 3729(a)(1)(C). “To state a claim for conspiracy under the FCA, a relator must allege (1) ‘a conspiracy to get a false or fraudulent claim allowed or paid’ and (2) ‘an act in furtherance of the conspiracy.’” *United States ex rel. Schieber v. Holy Redeemer Healthcare Sys., Inc.*, Civ. No. 19-12675, 2024 WL 1928357, at *7 (D.N.J. Apr. 30, 2024) (quoting *United States v. Medco Health Sys., Inc.*, Civ. No. 12-522, 2014 WL 4798637, at *11 (D.N.J. Sept. 26, 2014));

¹⁷ Because the Court has determined that the SAC fails to adequately plead facts necessary to establish falsity, the Court need not address the remaining elements of an FCA claim. See *United States ex rel. Portilla v. Riverview Post Acute Care Center*, Civ. No. 12-1842, 2014 WL 1293882, at *14-18 (D.N.J. Mar. 31, 2014) (declining to analyze remaining elements of an FCA claim after concluding that the relator could not state a claim for either factual or legal falsity). Nevertheless, the Court notes that even if Relators had adequately pled the falsity element, Relators FCA claims (Counts One and Two) would still fail to satisfy the “demanding” and “rigorous” materiality requirement. See *Escobar*, 579 U.S. at 194, 195 n.6; see also *Petratos*, 855 F.3d at 489 (outlining when materiality is or is not adequately pled). Here, Relators fail to meet this pleading requirement as they fail to allege that had the Government known of the alleged violations, such knowledge could influence the Government’s decision to issue reimbursements, or that the Government consistently refuses to make payments when laboratories submit claims for panel testing that may be deemed medically unnecessary. (See ECF No. 32 ¶¶ 21, 26, 31, 38, 83.) See also *Petratos*, 855 F.3d at 489 (noting that “[t]he mere fact that § 1395y is a condition of payment, without more, does not establish materiality,” and finding that “there are no factual allegations showing that CMS would not have reimbursed these claims had these [alleged reporting] deficiencies been cured” as well as relators failure to plead that CMS consistently refuses to pay for claims alleged in the complaint); *United States ex rel. Lampkin v. Pioneer Ed., LLC*, Civ. No. 16-1817, 2020 WL 4382275, at *3-5 (D.N.J. July 31, 2020) (dismissing multiple FCA claims because the relators failed to plead sufficient facts to show that the Department of Education would have ceased payments if it learned about any, or all, of the alleged falsification of students records).

see also United States ex rel. Atkinson v. PA. Shipbuilding Co., 473 F.3d 506, 513 (3d Cir. 2007). “[A]n agreement between two or more persons is the ‘essence’ of a conspiracy under the FCA.” *Schieber*, 2024 WL 1928357, at * 7 (quoting *United States v. Premier Educ. Grp., L.P.*, Civ. No. 11-3523, 2016 WL 2747195, at *19 (D.N.J. May 11, 2016)). Importantly, there can be no liability for conspiracy where there is no underlying violation of the FCA. *Petas*, 857 F.3d at 507 (quoting *Pencheng Si v. Laogai Research Found.*, 71 F. Supp. 3d 73, 89 (D.D.C. 2014)); *United States ex rel. Goebel v. Select Rehabilitation Inc.*, 696 F. Supp. 3d 48, 65 (E.D. Pa. 2023) (“Relators must also plead an underlying violation of the FCA” to state a claim for conspiracy).

Because Relators have not adequately pled an underlying violation of the FCA, Relators’ conspiracy claim must also be dismissed. *See Petras*, 857 F.3d at 507 n.53.¹⁸

B. Relators’ State Law Claims

Where a federal court has original jurisdiction over certain claims, it also has supplemental jurisdiction over all other related claims that form part of the “same case or controversy” under Article III of the United States Constitution. 28 U.S.C. § 1337(a); *see also United Mine Workers of Am. v. Gibbs*, 383 U.S. 715, 725 (1966) (same). Section 1337(c)(3) provides that district courts “may decline to exercise supplemental jurisdiction . . . if . . . the district court has dismissed all claims over which it has original jurisdiction.” As relevant here, “where the claim over which the district court has original jurisdiction is dismissed before trial, the district court must decline to decide the pendent state law claims unless considerations of judicial economy, convenience, and fairness to the parties provide an affirmative justification for doing so.” *Hedges v. Musco*, 204 F.3d 109, 123 (3d Cir. 2000) (emphasis in original). “Additionally, the federal court should be

¹⁸ Even if the Court did not dismiss Relators’ claims under 31 U.S.C. § 3729(a)(1)(A) or 31 U.S.C. § 3729(a)(1)(B), the SAC fails to plead facts sufficiently alleging an agreement between Genesis and Metropolitan to defraud the Government.

guided by the goal of avoiding needless decisions of state law . . . both as a matter of comity and to promote justice between the parties.” *Gibbs*, 383 U.S. at 726. Here, the Court has dismissed the federal claims at an early stage and declines to exercise supplemental jurisdiction over any potential state law claims at this time. *See also United States ex rel. Travis v. Gilead Sci., Inc.*, 596 F. Supp. 3d 522, 543 n.159 (E.D. Pa. 2022) (“Where no party has alleged a material difference between the standards applicable to the FCA and equivalent state laws, on a motion to dismiss these claims succeed or fall together.” (citing *United States ex rel. Petratos v. Genentech, Inc.*, 141 F. Supp. 3d 311, 322 (D.N.J. 2015))).

C. Defendants’ Request to Dismiss the SAC with Prejudice

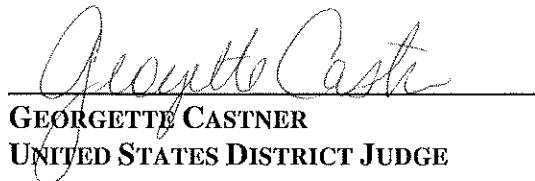
Defendants specifically request that this Court dismiss the SAC with prejudice because “[d]espite having two opportunities to amend, Relators have failed to cure significant pleading deficiencies in their Complaint.” (ECF No. 44-1 at 37.) “The law of this Circuit is that an initial dismissal, like this one, is presumptively without prejudice, and [the Court] see[s] no reason to depart from that rule.” *Perri*, 2019 WL 6880006, at *18. Therefore, the Court’s dismissal of the SAC is without prejudice.

IV. CONCLUSION

For the reasons stated above, and for other good cause shown, Defendants’ Motion to Dismiss (ECF No. 44) is **GRANTED**. Relators shall have thirty (30) days to file an amended complaint to the extent Relators can cure the deficiencies cited herein. Failure to file an amended complaint within that time will render the dismissal final. *See Mann v. A.O. Smith Corp.*, Civ. No. 21-2361, 2023 WL 2344225, at *2 (3d Cir. Mar. 3, 2023) (“A district court’s dismissal without prejudice for failure to state a claim is converted into a dismissal with prejudice if plaintiff ‘declar[es] his intention to stand on his complaint’ by failing to timely amend it. . . .”); *Hoffman v.*

Nordic Nats., Inc., 837 F.3d 272, 279 (3d Cir. 2016) (“When that 30-day period expired, the District Court’s decision became final.”). An appropriate Order follows.

Dated: February 26, 2025


Georgette Castner
GEORGETTE CASTNER
UNITED STATES DISTRICT JUDGE